

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 24 APR 2006

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Applicant's or agent's file reference 96700/862	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/US04/01773	International filing date (day/month/year) 23 January 2004 (23.01.2004)	Priority date (day/month/year) 24 January 2003 (24.01.2003)	
International Patent Classification (IPC) or national classification and IPC IPC: Please See Continuation Sheet USPC: 424/9.1,9.2,184.1,234.1,248.1;435/4,41,243,440,253.1,863			
Applicant ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) ___, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 24 August 2004 (24.08.2004)		Date of completion of this report 13 March 2006 (13.03.2006)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Rodney P. Swartz, Ph.D. <i>Valerie Bell-Harris</i> Telephone No. 571-272-1600	

Form PCT/IPEA/409 (cover sheet)(April 2005)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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**Box No. I Basis of the report**

## 1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
- pages 1-75 as originally filed/furnished
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:
- pages 83-87 as originally filed/furnished
- pages\* NONE as amended (together with any statement) under Article 19
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:
- pages 1/27-27/27 as originally filed/furnished
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/01773**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>1-43</u>	YES
	Claims <u>44-86</u>	NO
Inventive Step (IS)	Claims <u>1-43</u>	YES
	Claims <u>44-86</u>	NO
Industrial Applicability (IA)	Claims <u>1-86</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and Explanations (Rule 70.7)**

Claims 1-86 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 45-86 lack novelty under PCT Article 33(2) as being anticipated by Mahairas et al (*Journal of Bacteriology*, Vol. 178, No. 5, pages 1274-1282, 1996).

The claims are drawn to the use of an attenuated mycobacterium for the manufacture of a medicament wherein said mycobacterium has two deletions.

Mahairas et al teach *M. bovis* BCG containing deletions of RD1 to RD3 and exhibiting attenuated virulence (Abstract; page 1274, paragraphs 2 and 3; Material and Methods section, pages 1275-1276; Figure 2; Figure 3; Discussion, pages 1281-1282).

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**Box No. VII    Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof:

Page 12, line 11, "animal" should be "animals",  
Page 13, line 21, insert "a" between with and *M.*,  
Page 14, line 19, "that is that does" should be "that does",  
Page 43, line 29, "paranthesis" should be "parenthesis",

The drawings are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or content thereof:

Figure 1 does not display a label for "Panel a" as recited on page 14, line 25,  
Figure 17 shows Panel A and Panel B, but the brief description does not recite these panels,  
Figure 21 indicates two panels, but the brief description does not label these,  
Figure 22, indicates panels "A-I", but the brief description recites "a-i",  
Figure 23, indicates panels "A-E", but the brief description recites "a-e",  
Figure 24, indicates panels "A-F", but the brief description recites "a-f",  
Figure 25, indicates panels "A-E", but the brief description recites "a-f", the last panel does not appear to be labeled at all,

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**Box No. VIII** Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-86 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1-86 are indefinite for the following reason(s):

Claims 1 and 41 are recite "a method of treating a mammal", but does not recite what the treatment is for. Claims 2-40 and 42-43 depend from these claims but do not clarify the indefiniteness.

Claim 44 and 84 are directed to a use of a mycobacterium for manufacturing a medicament for treatment of a mammal, but does not recite what the treatment is for. Claims 45-83 and 83-86 depends from these claims but do not clarify the indefiniteness.

Claims 44-86 are drawn to the "use" of an attenuated mycobacterium for the manufacture of a medicament for treatment of a mammal. It is unclear what is meant by "use of". Does this mean that the attenuated mycobacterium is whole, broken up, or only certain parts of the cell are utilized/purified/isolated?

Claims 1-86 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims are not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because:

Claims 1-43 are drawn to a method of treating a mammal. Claims 44-86 are drawn to the use of a mycobacterium in the manufacture of a medicament for treatment of a mammal. Since the claims do not specify what the treatment is for, the entire scope of the claims are assessed. The instant disclosure only provides guidance/examples for treatment of mycobacterial infection, specifically, tuberculosis. The disclosure provides no guidance/examples for treatment of, e.g., cancer, mental illness, or other bacterial/viral diseases.

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**Supplemental Box**

**In case the space in any of the preceding boxes is not sufficient.**

Continuation of:

Continuation of IPC:

A61K 49/00( 2006.01),39/00( 2006.01),39/02( 2006.01),39/04( 2006.01);C12Q 1/00( 2006.01);C12P 1/00( 2006.01);C12N 1/00( 2006.01)